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Janie Miller
Secretary

To: Kentucky Vaccine Program (KVP) Providers who receive ROTARIX from KVP

From: Alicia Tindall, RN, BS

Date: March 23, 2010

Subject: Recommendation by CDC and FDA to temporarily suspend use of Rotarix vaccine

The Kentucky Immunization Program was notified on March 22, 2010, that the FDA is temporarily recommending that clinicians suspend the use of Rotarix, the rotavirus vaccine made by Glaxo Smith Kline. Components of a virus called porcine circovirus type 1 were found in the vaccine. Even though this virus is not known to cause illness in humans or other animals, it should not be present in the vaccine. Therefore, FDA is taking the precautionary measure of recommending that use of the vaccine be suspended. This suspension should give the FDA more time to gather additional information.

At this time, the Kentucky Immunization Program is requesting that providers put all the Rotarix vaccine in their stock together and label with a large sign stating “DO NOT USE”. Please keep the vaccine in the refrigerator at a temperature range of 35-46° F (2-8°C). CDC is not currently accepting returns of this vaccine. However, CDC is holding orders and stopping distribution of Rotarix.

CDC is not recommending the recall or revaccination of patients who have received Rotarix vaccine and no testing is recommended for patients who have received Rotarix vaccine. Parents of children who have received the vaccine should be reassured that this virus is thought to be harmless and does not impact the effectiveness of the vaccine.

Preliminary studies by the FDA on RotaTeq, the rotavirus vaccine made by Merck, have not shown the presence of the porcine circovirus 1 DNA. The FDA is working with Merck to confirm these results. Therefore, RotaTeq vaccine is available for rotavirus immunization during this period. CDC is currently working with Merck to ensure a stable supply of RotaTeq. At this time, please do not order ROTARIX vaccine for your clinics. However, you may order RotaTeq on the regular VFC order form. As a reminder, for children who have received one dose of Rotarix vaccine, the CDC recommends that clinicians complete the vaccination series with two doses of RotaTeq. The maximum age for any dose of rotavirus vaccine is eight months and zero days of age.

If you have questions regarding ordering, please contact the Kentucky Immunization Program at 502-564-4478. Clarissa Wilson is at extension 3734 (Clarissa.Wilson@ky.gov); Rita Lathrem is at extension 3914 (Rita.Lathrem@ky.gov); Judy Baker is at extension 3518 (Judy.Baker@ky.gov); and Laura Harrod is at extension 3855 (Laura.Harrod@ky.gov). For nursing questions, including questions regarding vaccine schedule and intervals between doses, please call 502-564-4478. Melissa Eastman, RN is at extension 3334 (Melissa.Eastman@ky.gov); Nancy Hamilton, RN is at extension 3516 (Nancy.Hamilton@ky.gov); and Alicia Tindall, RN is at extension 3585 (Alicia.Tindall@ky.gov).

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